Remarks

Reconsideration of this application is requested.

Claims 1, 2, 4-8, 10, and 32-34 are under consideration.

Claims 3 and 9 are canceled without prejudice in favor of a divisional or continuation application.

The rejection of all claims under 35 U.S.C. 112, first paragraph, as lacking enablement is traversed.

Ample experimental data have been provided in the specification. See, for example, pages 15-21 and FIGURES 7-11, inclusive. In addition, mouse Flk-1 (SEQ ID NO: 6) shares an approximately 85 percent homology with human KDR and plays an analogous role in mouse physiology to the KDR in humans. Accordingly, the mouse model is indeed an appropriate model in the present case.

The Berzofsky et al. publication is inapposite, and is inadmissible hearsay because it is not available as prior art, but has been cited for the purpose of establishing the truth of the matter stated therewithin.

Garmory et al. suffers from the same shortcomings as Berzofsky et al. This paper was published on 22 July 2002, after the filing date of the present application and again constitutes inadmissible hearsay. To the extent the Examiner seeks to rely on Garmory et al. to somehow bolster the non-enablement argument, the following passage from Garmory et al. at p. 348 must also be considered, however:

> The future for *Salmonella* vaccines looks very promising. A number of well-tolerated attenuated *S. enterica* var. Typhi strains have been shown to be immunogenic in clinical trials. These are clearly promising candidate typhoid vaccines. In addition, *Salmonella* vaccines have been shown to protect against a broad range of pathogens in animal models and preliminary results from clinical trials demonstrate that protective immunity against heterologous antigens is achievable. In addition, *Salmonella* vaccines have been successfully used to induce antitumour immunity [138,172,173]. Various problems have been encountered, particularly in the development of bivalent *Salmonella* vaccines, but numerous solutions have been obtained already and other problems are likely to be addressed in a similar manner.

The foregoing clearly militates against the Examiner's position.

Restifo et al. is also inadmissible hearsay to the extent this paper seeks to establish the truth of the matters stated therewithin. As a prior art reference, this paper is inapposite inasmuch as it neither shows nor suggests the presently claimed DNA vaccines.

The Gura reference is inapposite as well as inadmissible hearsay. Gura alleges that the known systems for identification of anticancer drugs are faulty, and that mouse xenograft models may not be reliable. The present claims, however, are not directed to anticancer drugs but to DNA vaccines.

Steinman et al. is likewise inadmissible hearsay to the extent it seeks to establish the truth of the matters stated therewithin. As a publication with a date of 9 July 2004, it is not available as prior art in the present case. The discussion in Steinman et al. about promising immunotherapy discoveries in mice that failed to translate in humans is but an undated historical account that sheds no light whatsoever on the enablement issues in this particular application.

As the Examiner himself has recognized, the level of skill in this particular field of art is high. Accordingly, it is submitted that the present specification, the working examples, and the presented data provide ample guidance to those skilled in the art to practice the claimed invention.

Respectfully submitted,

November 23, 2004

By _____
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this AMENDMENT AND RESPONSE UNDER RULE 111 is being transmitted by facsimile transmission to Fax No. 703-872-9306 on November 23, 2004.

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